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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/986,945	11/13/2001	Juan Mantelle	041457-0633	6420

22428 7590 04/04/2005

FOLEY AND LARDNER
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EXAMINER	
BERKO, RETFORD O	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 04/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/986,945	MANTELLE ET AL.	
	Examiner	Art Unit	
	Retford Berko	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

JC

DETAILED ACTION

Acknowledgement: The Amendment filed on 6/17/04 and the Information Disclosure Statement filed on 12/14/04 is acknowledged.

Withdrawal of Rejections:

1. The rejection of claims 1-17 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-6, 14-17 and 21-25 of U.S. Patent No. 6, 316, 022 is withdrawn in view of applicant's amendment and ensuing arguments.

2. The rejection of claim 1-21 under 35 U.S.C. 102(b) as being anticipated by Miranda et al (US5, 656, 286) is withdrawn in view of applicant's arguments.

Claim Rejections-35 USC Sec. 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The relevant part of the factual inquiries set forth in Graham v. John Deere & Co., 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and content of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue
3. Resolving the level of ordinary skill in the pertinent art
4. Considering objective evidence present in the application indicating obviousness or non-obviousness.

Claims 1-21 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Miranda et al (US5, 656, 286) in view of Miranda et al (US 5, 474, 783) further in view of Horstmann et al (US 5, 230, 898).

The scope of applicant's claims teach a pressure sensitive transdermal drug delivery composition wherein applicant claims that the delivery system comprises of a blend of acrylic polymers having shear resistance of 50 hours at 8 lbs/sq in and 72 degrees F or shear resistance greater than 100 hours at 8 lbs/sq in and 72 degrees F. According to applicant's claims, the drug is present in the composition at 1-40 wt/% and the molecular weight of the polymer ranges from 600, 000 to 1, 000,000 daltons. Applicants's claims further teach a method of producing the formulation entailing blending of polymers, drug and solvent. The specification describes various examples of polymer components that applicant used in order to achieve the composition characteristics claimed in the invention and commercial nomenclature for the polymers (see pages 20-21, tables 1-3).

As discussed above, Patent '286 teaches a blend of at least two polymers in combination with a drug (s) such as nicotine for transdermal delivery in a pressure-sensitive adhesion composition (abstract). Patent '286 teach the use of commercial polymers for formulating the composition equivalent to what applicant used (e.g. polymethacrylate, col 8, table 1A; Bio-PSA X7-4503, col 47; Duro-Tak 80-1196; col 53) as well as the disclosure of other polymers with molecular weight less than 2,000,000 (col 3, lin 10). Patent '286 teaches that multiple polymer adhesives not only functions as a carrier matrix for the drug, but enhances the rate of release of the drug and hence the transdermal permeation rate (col 7, lin 5). Patent '286 further teaches the process for formulating the composition equivalent to what applicant claims (seel col 35, lin 15-

20 and col 65, lin 30 continuing to col 65). Patent '286 does not teach the pressure-sensitive transdermal drug delivery system in the composition nor the exact polymers with molecular weights ranging from 600,000 to 1, 000,000 daltons, shear resistance of 100 and above at 8 lbs/sq in at 72 degrees F.

Patent '783 teaches the use of Bio-PSA X7-3027, polyacylate adhesive and Duro-Tak 80-1194 polymers in combination with drugs for forming transdermal drug delivery composition (col 16, lin 5-55). Patent '783 further teaches that dermal compositions using these polymers can be produced by a variety of methods known in the preparation of drug-containing adhesive preparations that can be adjusted to obtain delivery rates of drug while maintaining acceptable shear, tack and peel adhesive properties (abtract).

One of ordinary skill in the art would be motivated to use different polymers combinations, drug (e.g. nicotine) in place of the nitroglycerine used by Miranda et al (Patent '783) in amounts that would produce a dermal formulation that has pressure sensitive adhesive properties and shear resistance as claimed by applicant. One of ordinary skill would expect to obtain desirable transdermal permeation rate of the drug. Therefore, the invention as a whole would have been prima facie obvious at the time applicant made her invention.

The scope of the disclosure in Horstmann et al (Patent '898) wherein a transdermal drug delivery system comprising basic polymers such as polyacrylic acid ester containing nicotine (col 3, lin 45 continuing through col 4, lin 40) teach that the transdermal drug delivery composition exhibits pressure-sensitive adhesive properties, as claimed by applicant. One of ordinary skill in the art would be motivated to use different combinations of polymers and drugs that give formulations with desirable shear, tack and peel characteristics as claimed by applicant.

One of ordinary skill would expect to obtain transdermal drug delivery system having uptimal dermal permeation rate for the drug to be delivered. Therefore, the invention as a whole would have been prima facie obvious at the time applicant made her invention.

Response To Arguments

Applicant argues that neither Miranda '286 nor Miranda '783 disclose or suggest a transdermal drug delivery system comprising a blend of polymers wherein one of said one or more polymers has a high shear resistant acrylic-based polymer. Applicant also argues that the prior art of record does not disclose a therapeutically effective amount of one or more drugs, at least one of which is of low molecular weight and liquid at or about room temperatures which is substantially free of water and liquids having a boiling point below processing temperatures; and equal to or greater than the normal boiling points of the low molecular weight drugs and that there is no motivation in the references to arrive at a composition which includes one or more polymers wherein one of said one or more polymers is a high shear resistant acrylic-based polymer. Finally, applicant argues that here is no teaching in Miranda '286 or Miranda '783 of the importance of high shear resistance when delivering low molecular weight drugs that are liquid at room temperature.

In response, applicant's invention is drawn toward a adhesive transdermal drug delivery system comprising a blend of acrylic based polymers and drugs. Applicant provides as examples of the invention selegiline-polymer mixture, polysiloxane or polyacrylate (examples 1-3, specification at pages 19-21). Patent '286 discloses the use of a blend of at least two polymers in combination with a drug (s) for transdermal delivery in a pressure-sensitive adhesion composition (abstract). Also, Patent '286 discloses use of commercial polymers for formulating

the composition equivalent to what applicant used (e.g. polymethacrylate, col 8, table 1A; Bio-PSA X7-4503, col 47; Duro-Tak 80-1196; col 53); the polymers having shear resistance of 100 and above at 8 lbs/sq in at 72 degrees F.

According to Miranda et al the pressure-sensitive adhesive composition of the delivery device comprising polyacrylic polymer can be formulated to maintain acceptable shear tack ((Patent '286, col 10, lin 15-24). Furthermore, Miranda et al disclose that the multiple polymer adhesive system is formulated to have desirable characteristics including good adherence to skin, ability to peel off or otherwise removed without substantial trauma to skin and retention of tack with aging (col 9, lin 15-45). Furthermore, the scope of the disclosure in Horstmann et al (Patent '898) wherein a transdermal drug delivery system comprising basic polymers such as polyacrylic acid ester containing nicotine (col 3, lin 45 continuing through col 4, lin 40) teach that the transdermal drug delivery composition exhibits pressure-sensitive adhesive properties, as claimed by applicant. One of ordinary skill in the art would be motivated to use different combinations of polymers and drugs that give formulations with desirable shear, tack and peel characteristics as claimed by applicant. One of ordinary skill would expect to obtain transdermal drug delivery system having uptimal dermal permeation rate for the drug to be delivered. Conclusion: No claims are allowed.

The following prior ar is made of record as pertinent to applicant's claims although the reference is not relied upon in the present office action for the rejection of claims. The reference discloses the use of specific polymers cited in applicant's specification as examples of the current invention (col 14, lin20-65; continuing to col15, lin 1-35; compare with specification at

pages 19-21). The reference is not used because it does not teach all the requirements of the claims as modified.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Respectfully,

ROB

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Retford Berko** whose telephone number is571-272-0590. The examiner can normally be reached on M-F from 8.00 am to 5.30 pm

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Thurman K Page**, can be reached on 571-272-0602.

RoB

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600